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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/522,055	03/09/00	CHENG	Y 044574-5064

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EXAMINER	
PATTEN,P	
ART UNIT	**PAPER NUMBER**
1651	7

DATE MAILED: 11/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/522,055	Applicant(s) Cheng et al.
	Examiner Patricia Patten	Group Art Unit 1651

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-24* is/are pending in the application.

Of the above, claim(s) *5-10 and 13-24* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-4, 11, and 12* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Applicant's election of Group I, Claims 1-4 and 11-12 with traverse in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-4 and 11-12 have been presented for examination on the merits.

Claims 5-10 and 13-24 have been withdrawn from consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating certain types of tumors, does not reasonably provide enablement for a method for treating any disease. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. .

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because effective treatments for disease

conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments.

Nowhere in the instant specification is there any guidance and/or working examples where the composition of the present invention has treated anything but tumors. In the present instance, the claimed invention encompasses a veritable plethora of possible treatments which the present invention may treat. The inadequate disclosure coupled with a lack of representative examples and the art recognized unpredictability with respect to the effects regarding the bioactivity of such compounds thus preclude the uses of compositions within the scope of the presently claimed invention by the skilled artisan without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 11 recite the phrase:' material from a plant species.' 'Material' is indefinite in that the meets and bounds of the claim language is not clearly delineated. It is not known

exactly what 'material' the claim is referring to. Is it an aqueous extract, an alcoholic extract, or a particular part of the plant? Each of these examples may contain different phytochemicals which may necessarily exhibit different effects. Correction is necessary.

Claims 1 and 11 further recite the claims 'one or more chemotherapeutic compounds.' This term is indefinite in that the meets and bounds of the claim language is not clearly delineated. It is not known exactly what the composition is, since a myriad of chemotherapeutic compounds may be administered. It is further not known what type of effect a composition comprising, say 10 known chemotherapeutics would have on an individual. The composition as claimed is not clearly defined with the recitation of 'one or more.' Correction is necessary

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramadoss et al. (US 6,048,847) in view of Chen et al. (US 5,665,393) and Okuda et al. (US 4,618,495). Claims 1-4 and 11-12 are drawn to a composition comprising material from Scutellaria, Glycyrrhiza, Ziziphus and Paeonia admixed with known cancer chemotherapeutic

drugs and further admixed with a pharmaceutically acceptable carrier. Claims are further drawn to specific species of the Genera named above, specifically, *Scutellaria baicalensis*, *Glycyrrhiza uralensis*, *Ziziphus jujuba* and *Paeonia lactiflora*. Claim 11 is drawn to a method for treating a disease with the before mentioned composition.

Scutellaria baicalensis was known to contain constituents which inhibited cancer cell proliferation (Chen et al. Col.3, line 28 and Col.4, Table 1).

Glycyrrhiza uralensis and *Paeonia lactiflora* were known to contain anti-tumor activity. Okuda et al. (US 4,618,495) disclosed that extracts from both of these plants were useful for reducing cancer symptoms (Abstract).

Ramadoss et al. (US 6,048,847) taught that betulinic acid, which was derived from certain plants such as *Ziziphus jujuba* (Col. 6, line 48) had anti-tumor effects (Abstract).

Compositions such as irinotecan formulations, 5-fluorouracil, VP-16 and beta-L-Dioxolane-cytidine were all well known anti-cancer agents, as was admitted by Applicant's in the Instant disclosure (pp.12-16).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art to treat and/or aid in treating cancer and/or tumors. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

It would have been further apparent to one of ordinary skill in the art to create a method for treating cancer with the instantly claimed composition since all of the ingredients are known to treat and/or aid in treating cancer. One of ordinary skill in the art would have had a reasonable expectation that since all of the ingredients were known in the art to inhibit and/or aid in cancer individually, that a combination of the ingredients would have displayed an additive effect when administered to an individual in need of treatment.

Accordingly, the instant claims, where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

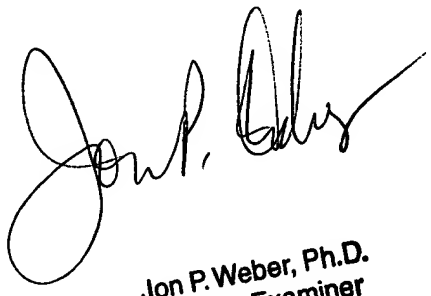
From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jon P. Weber, Ph.D.
Primary Examiner